OCT 5 2010

510(k) Summary

K093816

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: May. 20, 2009

1. Company and Correspondent making the submission:

Name – Medien International Co., Ltd.
Address – 1-40, Hanlim Human Tower #501, Geumjeong-dong, Gunpo-si,
Gyeonggi-do, 435-862, Republic of Korea
Telephone – +82-31-451-9466
Fax – +82-31-451-9467
Contact – Jae-Hyun, Lee / RA Manager
E-mail – jhlee@medien.co.kr

2. Device :

Trade/proprietary name	: Galaxy 900
Common Name	: Digital Radiography System
Classification Name	: Stationary X-ray System

3. Predicate Devices :

Manufacturer	: Imaging Dynamics Co., Ltd.
Device	: Xaminer
510(k) Number	: K061595(Decision Date – 8. 17. 2006)

4. Classifications Names & Citations :

21CFR 892.1680, KPR - Stationary X-ray System, Class 2

5. Description :

5.1 General

The Digital Radiography System, Galaxy is an optical based digital x-ray imager. This device should be integrated with an operating PC. The visible light is deflected by a mirror to a high-resolution CCD camera that produces a digital image. It can do to utilize as digitalizing x-ray images and transfer for radiography diagnostic.
The BLADE software acquires X-ray image and viewing the image.
Get image from detector, process it to ease the diagnostic, save it in database and manage it.

5.3 Product features

- One Charge Coupled Device (CCD) armed with one lens.
- 17" x17" imaging area.
- Wide dynamic range with 16-bit digitization
- SW is designed to be operated on MS Windows XP operating system
- Image process parameters are selectable according to the body part to make best images for diagnosis
- DICOM3.0 standard compliance
- Image Format : 3,056 x 3,056
- High Resolution image : with 3.5 lp/mm

6. Indication for use :

The Galaxy 900 is integrated into the user's stationary radiography system. This typical configuration permits a qualified/trained doctor or technologist to take a range of head-to-toe diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient sitting, standing or lying in the prone or supine positions in an integrated system.
The Galaxy 900 is not intended for mammography.

7. Comparison with predicate device :

Medien International Co., Ltd. believes that the Digital Radiography System (Galaxy 900) is substantially equivalent to to Xaminer of Imaging Dynamics Co., Ltd..

8. Safety, EMC, Biocompatibility and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2(2001).
Biocompatibility testing was conducted in accordance with Standard ISO 10993-1.
Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" was performed.
All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Medien International Co., Ltd. concludes that the Digital Radiography System(Galaxy 900) is safe and effective and substantially equivalent to predicate devices as described herein.

10. Medien International Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: May. 20, 2009

9. Company and Correspondent making the submission:

Name – Medien International Co., Ltd.
Address – 1-40, Hanlim Human Tower #501, Geumjeong-dong, Gunpo-si,
Gyeonggi-do, 435-862, Republic of Korea
Telephone – +82-31-451-9466
Fax – +82-31-451-9467
Contact – Jae-Hyun, Lee / RA Manager
E-mail – jhlee@medien.co.kr

10. Device :

Trade/proprietary name	: Galaxy 1600
Common Name	: Digital Radiography System
Classification Name	: Stationary X-ray System

11. Predicate Devices :

Manufacturer	: Imaging Dynamics Co., Ltd.
Device	: Xplorer 1000
510(k) Number	: K992955 (Decision Date – 2. 6. 2000)

12. Classifications Names & Citations :

21CFR 892.1680, KPR - Stationary X-ray System, Class 2

13. Description :

5.1 General

The Digital Radiography System, Galaxy is an optical based digital x-ray imager. This device should be integrated with an operating PC. The visible light is deflected by a mirror to a high resolution CCD camera that produces a digital image. It can do to utilize as digitalizing x-ray images and transfer for radiography diagnostic.
The BLADE software acquires X-ray image and viewing the image.
Get image from detector, process it to ease the diagnostic, save it in database and manage it.

5.3 Product features

- One Charge Coupled Device (CCD) armed with one lens.
- 17" x17" imaging area.
- Wide dynamic range with 16-bit digitization
- SW is designed to be operated on MS Windows XP operating system
- Image process parameters are selectable according to the body part to make best images for diagnosis
- DICOM3.0 standard compliance
- Image Format : 4,096 x 4,096
- High Resolution image : with 4.6 lp/mm

14. Indication for use :

The Galaxy 1600 Digital CCD X-Ray Detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. The Galaxy 1600 is not intended for mammography.

15. Comparison with predicate device :

Medien International Co., Ltd. believes that the Digital Radiography System (Galaxy 1600) is substantially equivalent to to Xaminer of Imaging Dynamics Co., Ltd. and Xplorer 1000 of Imaging Dynamics Co., Ltd..

16. Safety, EMC, Biocompatibility and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1 was performed, and EMC testing was conducted in accordance

with standard IEC 60601-1-2(2001).
Biocompatibility testing was conducted in accordance with Standard ISO 10993-1.
Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" was performed.
All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Medien International Co., Ltd. concludes that the Digital Radiography System(Galaxy 1600) is safe and effective and substantially equivalent to predicate devices as described herein.

10. Medien International Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -- WO66-G609
Silver Spring, MD 20993-0002

Mr. Charles Mack
Principal Engineer
Medien International Co., Ltd.
77325 Joyce Way
ECHO OR 97826

OCT 5 2010

Re: K093816
Trade/Device Name: Digital Radiography System/Galaxy 900 and Galaxy 1600
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: September 13, 2010
Received: September, 2010

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

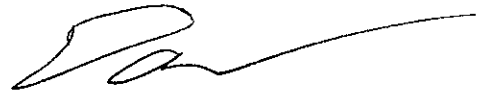
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small, Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number(if known): K093816

Device Name: Digital Radiography System/ Galaxy 900

Indications for Use:

The Galaxy 900 is integrated into the user's stationary radiography system. This typical configuration permits a qualified/trained doctor or technologist to take a range of head-to-toe diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient sitting, standing or lying in the prone or supine positions in an integrated system.

The Galaxy 900 is not intended for mammography.

Prescription Use X AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093816